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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/997,734	11/29/2001	Pamela C. Yelick	10498-00031	4087
22910	7590	11/06/2003	EXAMINER	
BANNER & WITCOFF, LTD. 28 STATE STREET 28th FLOOR BOSTON, MA 02109-9601			BISSETT, MELANIE D	
			ART UNIT	PAPER NUMBER
			1711	

DATE MAILED: 11/06/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/997,734	YELICK ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Melanie D. Bissett	1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 05 August 2003.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 5-33 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 33 is/are allowed.
- 6) ☒ Claim(s) 5-8, 15-22 and 29-32 is/are rejected.
- 7) ☒ Claim(s) 9-14 and 23-28 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

#### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All   b) ☐ Some \*   c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)                  | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____  |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)         | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other:  |

1. The rejections based on 35 USC 112, 102, and 103 have been withdrawn based on the applicant's amendments. However, a new rejection has been set forth as necessitated by amendment.

***Claim Rejections - 35 USC § 103***

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 5, 15-19, and 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al. in view of Elia.

4. Mooney discloses methods for regenerating dental and oral tissues by incorporating dental cells into a structural matrix (abstract). Oral tissue cells grow on a three-dimensional support network to produce new tissue (col. 3 line 64-col. 4 line 19), and the materials are then implanted into subjects (col. 4 lines 20-31). The matrix materials include biodegradable polylactides, polyglycolides, and polylactide/polyglycolide copolymers (col. 11 lines 20-30). The matrix materials may be coated with collagen coating agents (col. 11 lines 59-65). Examples show that cells are incorporated into the matrix at high concentrations and are incubated on the scaffolds for periods longer than 1 hour. Although gingival and dental pulp-derived cells are noted for incorporation into the matrix, no specific mention is made of tooth germ cells (col. 12 lines 44-51; col. 13 lines 21-45).

5. Elia discloses methods for the growth of organs, where genetic materials are placed in the body [0004]. The reference exemplifies the use of tooth germ cells for

generating tooth tissue, where the germinal cells are chosen for their ability to transcribe root structure and facilitate the generation of the tooth germ (example 1). Therefore, it is the examiner's position that it would have been prima facie obvious to use tooth germ cells in Mooney's invention to facilitate the growth of tooth germ tissue in the matrix.

6. Claims 6-8 and 20-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mooney et al. in view of Elia as applied to claims 5, 15-19, and 29-32 above, and further in view of Lichkus et al.

7. Mooney et al. and Elia apply as above, where Mooney notes that the three dimensional structure resembles the structure from which the cells are taken (col. 14 lines 1-8). However, the reference does not specify the molding of the scaffold or the shaping into a human tooth. Lichkus teaches a conventional process for producing artificial teeth, where the materials to be implanted are molded into the shape of human teeth to provide teeth with convincing appearances (abstract; col. 11 lines 35-45). By conventional teaching, it is the examiner's position that it would have been prima facie obvious to shape the scaffold of the combined inventions of Mooney and Elia by molding into a human tooth to provide an end product with a convincing appearance.

***Allowable Subject Matter***

8. Claim 33 is allowed.

9. Claims 9-14 and 23-28 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

10. The following is a statement of reasons for the indication of allowable subject matter:

11. The closest prior art, Mooney et al. (US 5,885,829 A), discloses methods for regenerating dental and oral tissues by incorporating dental cells into a structural matrix. Tooth cells including gingival and dental pulp cells are noted for incorporation into the scaffold matrix. Although the examiner holds that it would have been obvious to use tooth germ cells in Mooney's invention, the cited references do not specify the source of the tooth germ cells as enamel organ and pulp organ cells. Also, Mooney does not specify the implantation of the generated tooth tissue to the omentum of a host animal. Thus, it is the examiner's position that the claimed implantation step and use of specified enamel organ and pulp organ cells in the applicant's claimed method provide a novel and unobvious step over the prior art.

#### **Conclusion**

12. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melanie D. Bissett whose telephone number is (703) 308-6539 or (571) 272-1068 after December 2003. The examiner can normally be reached on M-F 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (703) 308-2462. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0661.

  
RABON SERGENT  
PRIMARY EXAMINER

mdb